

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Bradford C. Webb

Serial No.: 08/055822

Filed: April 4, 1993

For: Synthetic Viscoelastic
Material for Ophthalmic
Applications

Declaration of John D. Hunkeler
Submitted Under 37 CFR 1.132

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

I, John D. Hunkeler, M.D., F.A.C.S., declare that:

1. I am a medical Doctor with 27 years of medical experience, of which 23 were in the specialty of ophthalmology.
2. I obtained my Bachelor of Arts degree from Harvard College in 1963.
3. I was awarded a Medical degree from University of Kansas School of Medicine in 1967.
4. I performed a residency in ophthalmology from 1970 to 1973 at the University of Kansas School of Medicine.

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5. I was appointed to be a diplomate in American Board of Ophthalmology in 1976.

6. I was appointed to be a fellow in the American College of Surgeons in 1977.

7. I was Chairman of the Department of Ophthalmology at Trinity Lutheran Hospital from 1981 to 1983.

8. I began a two year term as President of the American Society of Cataract & Refractive Surgery in 1992.

9. I have published seven articles discussing various aspects of corneal and cataract surgery within the last ten years in nationally recognized ophthalmic journals.

10. I have performed over 10,000 ophthalmic surgical procedures during my career.

11. I am familiar with a range of viscoelastic materials, including cellulosic based materials, used during cataract and lens implant surgery.

12. I am familiar with the material marketed under the name of "Cellugel" materials, said material supplied to me by Dr. Brad Webb of Vision Biology, Inc. It is my understanding that this material is made in accordance with the teachings and is covered by the claims of United States Patent Application 08/055,822 filed April 4, 1993.

13. When using cellulosic based viscoelastic materials other than Cellugel[™] materials, I have often been hampered in surgery by the low static viscosity of these materials. Such materials do not provide sufficient viscosity to insure adequate anterior chamber volume because they rapidly flow out of the eye through the incision, and are therefore not as useful in providing the necessary protection required during modern cataract surgery procedures.

14. Another problem I have encountered with other materials used for the same purpose is that they are sometimes slightly cloudy. This cloudiness makes it difficult to see clearly where the surgery is taking place. It is my understanding that this cloudiness is caused by particulates and bubbles inside the material. I have been informed that the process claimed in the subject patent application removes all particulate matter greater than 0.5 μ and all dissolved gases from Cellugel[™] materials. In my experience, because of this unique process, Cellugel[™] materials are always very clear.

15. Yet another problem, which may be encountered with other cellulosic materials, is the occasional high postoperative pressure created in the eyeball associated with these materials blocking the trabecular mesh work. Unless corrective action is taken this high pressure might cause blindness. In my experience, I have never noticed a dangerously high postoperative intraocular pressure when I have used Cellugel[™] materials during cataract surgery.

16. A further problem encountered with other cellulosic materials is that they are not sufficiently lubricous. A highly lubricous material is more protective of the delicate eye tissue as

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artificial lenses and surgical instruments will slide harmlessly over tissue that is covered with Cellugel™ materials. The highly lubricous nature of Cellugel™ materials gives me confidence that the use of this material will reduce the incidence of tissue damage in the eye.

17. I have no knowledge of the existence of a cellulosic based viscoelastic product that has the unique combination of properties all of which are requirements of a useful material for cataract procedures demonstrated by the Cellugel™ materials product, namely both high static viscosity, viscoelasticity, clarity, high lubricousness and absence of negative postoperative events.

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DECLARATION

18. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that all statements were made with the knowledge that willful false statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereupon.

Dated: March __, 1994


Dr. John D. Hunkler
for U.S. Patent Application
No. 08/055822